



Trial Day 2  
Volume 1 of 1  
November 13, 1997

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
NORTHERN DIVISION

GLAXO WELLCOME INC., et al.

Plaintiffs

v.

PHARMADYNE CORPORATION, et al.

Defendants

Civil Docket No. AMD-96-455  
And  
Civil Docket No. AMD-96-1853  
(Consolidated)

Baltimore, Maryland  
November 13, 1997  
10:10 a.m.

The above-entitled matter came on for trial before  
The Honorable Andre M. Davis.

A P P E A R A N C E S

On behalf of the Plaintiffs:

Stephen Judlowe, Esquire  
John Henry Lewin, Jr., Esquire  
Brian P. Murphy, Esquire  
Robert Gibbons, Esquire  
Regina Ambery, Esquire  
Jason Lief, Esquire

On behalf of the Defendants:

James Rubin, Esquire  
Alan H. Bernstein, Esquire  
Robert S. Silver, Esquire  
John M. Seeberger, Esquire  
Deborah K. Besche, Esquire

Reported by: Betty Lou Walls, RPR

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1	I N D E X					
2	WITNESS:	DIRECT	VOIR DIRE	CROSS	REDIRECT	RECROSS
3	David R. Long	403		428		
4	Paul E. Wray	469				
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1 the examiner's rejection, and toward the bottom of the page,  
2 again, this was referenced earlier in Dr. Long's testimony,  
3 the applicant states, quote: However, the purpose for which  
4 ethanol has been included has been either as a solvent or as  
5 a preservative against bacterial contamination. There was,  
6 however, no reason to suppose that either of these functions  
7 of ethanol would have had any beneficial effect in terms of  
8 limiting the degradation of ranitidine in aqueous  
9 formulations thereof. Close quote.

10 Do you agree with that statement?

11 A Yes, I agree. It's consistent with my experience also.

12 Q There was reference earlier to Tagamet syrup. What is  
13 the active ingredient in Tagamet?

14 A The active ingredient in Tagamet is the chemical entity  
15 Cimetidine.

16 Q It's not ranitidine hydrochloride, right?

17 A No, it's dissimilar.

18 Q It's a free-based salt?

19 A That's correct.

20 Q As of the effective date of the filing this  
21 application, which is December 12, 1986, the date that Dr.  
22 Long files his very first application in the United Kingdom,  
23 as of that date are you aware of any publication prior to  
24 that date that discloses the purpose of why ethanol was added  
25 to Tagamet?

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1 A No, I'm not aware.

2 Q And prior to that date, December 12, 1986, are you  
3 aware of any publication suggesting that adding ethanol to  
4 Tagamet syrup would enhance the chemical stability of the  
5 solution?

6 A No, I'm not.

7 Q Are you aware of any publication prior to that date  
8 suggesting that adding ethanol to any pharmaceutical  
9 formulation would enhance chemical stability of the solution?

10 A No, I'm not.

11 Q Dr. Wray, based on this filing, did the examiner  
12 ultimately allow all of the claims in the patent application?

13 A He did allow all the claims ultimately. I think there  
14 was data submitted -- oh, yes, there was data submitted at  
15 this time to this rejection, and it was allowed after that,  
16 yes.

17 Q Thank you, Dr. Wray. You may set aside that exhibit  
18 and I would like to change topics now and discuss the  
19 defendants' development of generic ranitidine oral solution.

20 Dr. Wray, you indicated earlier that you have read  
21 the UDL Laboratory notebooks and document reports pertaining  
22 to UDL's development of ranitidine oral solution?

23 A Yes, I did.

24 Q You read all the notebooks of Dr. Gullapalli which  
25 contain description of his experiments?

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Trial Day 13  
Volume 1 of 2  
December 18, 1997

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IN THE UNITED STATES DISTRICT COURT  
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NORTHERN DIVISION

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Plaintiffs

v.

PHARMADYNE CORPORATION, et al.

Defendants

Civil Docket No. AMD-96-455  
and  
Civil Docket No. AMD-96-1853  
(Consolidated)

Baltimore, Maryland  
December 18, 1997  
10:00 a.m.

The above-entitled matter was continued on for trial before  
The Honorable Andre M. Davis

A P P E A R A N C E S

On Behalf of the Plaintiffs:  
Stephen Judlowe, Esquire  
John Henry Lewin, Jr., Esquire  
Brian P. Murphy, Esquire  
Robert G. Gibbons, Esquire  
Regina Ambery, Esquire  
Jason Lief, Esquire

On Behalf of the Defendants:  
James Rubin, Esquire  
Alan H. Bernstein, Esquire  
Robert S. Silver, Esquire  
John M. Seeberger, Esquire  
Deborah K. Besche, Esquire



1 Q Is there anywhere in this reference where it discloses why  
2 alcohol was added?

3 A No.

4 Q Dr. Wray, you have been here for the entire trial, and you  
5 have heard all or just about all of the testimony; is that  
6 right?

7 A Yes.

8 Q You were here for Dr. Long's testimony?

9 A Yes.

10 Q Did Glaxo use ethanol in their original formulation for  
11 ranitidine hydrochloride oral solution?

12 A No, they did not.

13 Q At that time, did Glaxo know about, based on the evidence  
14 that you heard, Tagamet syrup containing alcohol or ethanol?

15 A Yes. They must have known.

16 Q Can you tell us why, in your opinion, based on the  
17 evidence, Glaxo did not use ethanol at least in its original  
18 formulation for Zantac oral solution?

19 A I believe they did not include ethanol because they felt  
20 they did not need it.

21 Q With respect to the active ingredient in the Tagamet syrup,  
22 specifically ranitidine, is that, in your opinion, chemically  
23 the same kind of compound as ranitidine?

24 A No, it is not. It's quite different.

25 Q Can you explain the differences, please?

1 A Well, the ranitidine hydrochloride is considered an  
2 enamine, which has a specific chemical structure. And the  
3 cimetidine is a guanidine product. Specifically, it's a  
4 cyano-derivative of guanidine. They have totally different  
5 ring structures in addition to these differences in the side  
6 chains.

7 Q Is either ranitidine or cimetidine considered an amide?

8 A No, they are not.

9 Q Dr. Wray, I am going to put up on the easel a couple of  
10 exhibits. Specifically, I am going to start with claim 1 of  
11 the '249 patent, and I am going to put up Plaintiffs' Exhibit  
12 Number 419.

13 (Pause in the proceeding.)

14 Q Dr. Wray, when I began your examination this morning, I  
15 asked you if you had made a comparison of the prior references  
16 to the claims of the '249 patent, and you indicated that you  
17 did; is that correct?

18 A Yes, I did.

19 Q Does Plaintiffs' Exhibit 419, which is on the left-hand  
20 easel, accurately reflect your opinion and analysis of the  
21 prior references cited by defendants in connection with the  
22 '249 patented invention?

23 A Yes, it does.

24 Q Beginning with Plaintiffs' Exhibit 419 and, where  
25 appropriate, making reference to the '249 patent claim 1, which